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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,083	01/16/2002	Yuichi Yamamoto	2002-0031A	6146

513 7590 02/11/2005

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EXAMINER	
CHIN, BRAD Y	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,083	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	Brad Y. Chin	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☒ Claim(s) *1,2 and 4-11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ ~~Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)~~ Paper No(s)/Mail Date *1/16/02 & 4/16/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 1-2 and 4-11 are objected to because of the following informalities:

In claim 1, Applicant provides preamble language stating, "a method for production of a sealing tool". It is Examiner's belief that the claimed subject matter does not relate to "production of a sealing tool", rather the preamble provides intended use language relating to preparation of a sealing tool or sterilizing a sealing tool. Accordingly, Examiner has examined the claimed language with such intended use preamble language in mind.

In claim 1, Applicant's method provides for "one sterilization pulse to a combination of 70 g/pulse of an aqueous hydrogen peroxide solution (a concentration of 35% by weight) injection amount x 3 pulses and 20 pulses of an aeration." Examiner understands the method to provide for 3 pulses of 70g/pulse of aqueous hydrogen peroxide solution followed by 20 pulses of clean gas aeration. Applicant should amend the claim language to be more clear and precise.

In claims 2, 3, and 7, Applicant should remove the words, "thereby carrying out the sterilization treatment.

In claim 6, Applicant should remove the words, "in advance".

In claims 8, 9, and 11, Applicant should amend the language, "at least one member selected from a" to "at least one member selected from the group consisting of" to comply with proper Markush group language. See MPEP 2173.05(h).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claims 1-2 and 4-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant fails to provide a description enabling one of ordinary skill in the art to determine the subject matter relating to setting a filling rate in the sterilization bag to 45% or 20%; 50% or 20%; or 12 to 55%, respectively. It is Examiner's understanding that filling rates routinely use a flow rate (volume/time) rather than a percentage (%).

Additionally, Applicant fails to describe the subject matter in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to account for the activation of the gaseous hydrogen peroxide in generating the active oxygen and hydroxide radical, identified in claim 1, as the members for sterilizing the gaskets in the sterilization unit. Applicant merely states, "it is understood that hydrogen peroxide molecules are decomposed on the sterilization conditions and generates at least one of the group consisting of the active oxygen and hydroxide radical, the active oxygen or hydroxide radical thus generated or both of them exert(s) an oxidation action on the intended bacteria cells and the like which are to be oxidized and decomposed."

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1-2 and 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform to current U.S. practice. They appear to be a literal translation into English from a foreign document and are

replete with grammatical and idiomatic errors. The following are examples of such non-conformity:

- In claims 1-11, Applicant fails to provide gerunds in claiming the steps of his method, i.e. in claim 1, beginning on line 8, Applicant should amend the claim language to state, "introducing the gaseous hydrogen peroxide into the sterilization unit...holding the gaseous hydrogen peroxide in the sterilization unit for...pulsing the sterilization unit...aerating the sterilization bag with twenty pulses of clean gas", etc.
- In claims 1, 2, and 7, Applicant's claim language stating various filling rates to be used for sterilizing a gasket for a normal-type syringe and a gasket for a large-sized syringe, respectively, is indefinite and fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Based on such claimed language, one of ordinary skill in the art would not understand the relationship between the percentages and filling rates, in light of the specification.
- In claim 4, Applicant's claim language "...to be carried out next to a sterilization pulse" contains an idiomatic error. It is presumed that the sterilization pulse is followed by or in combination with a number of aeration pulses. Applicant should amend the claim language for clarity.
- In claims 4 and 5, Applicant claims the number of aeration pulses. One of ordinary skill in the art would not understand with particularity how many aeration pulses Applicant is claiming when Applicant uses the claim language, "or more". Accordingly, the claim language of claims 4 and 5 fail to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Childers et. al. [U.S. Patent No. 5,492,672] in view of Anderson et. al. [U.S. Patent No. 4,937,046]; further in view of non-patent literature, "Syringes – Stanley Gomez Sdn. Bhd., Malaysia, 1999; and further in view of Jacobs et. al. [U.S. Patent No. 4,643,876].

Childers teaches a method for sterilizing instruments and other devices having long narrow lumens, e.g. a syringe, comprising the steps of:

holding a sterilization unit under high vacuum (vacuum pump 16; See Specification, col. 3, lines 5-6 – the chamber and devices are in a vacuum; See Specification, col. 14, lines 55-59 – "deep vacuum"; See Specification, col. 9, lines 23-24 – a vacuum is drawn within the sterilization chamber 12);

introducing hydrogen peroxide in a concentration of 35 % by weight, by pulsing the sterilant vaporized hydrogen peroxide into the sterilization unit (See Specification, col. 4, lines 7-12 – preferred sterilant is hydrogen peroxide vapor generated from an aqueous solution of 30-wt % hydrogen peroxide. Hydrogen peroxide in other concentrations would also be suitable for practicing the method of the present invention; See Specification, col. 5, line 65 to col. 6, line 12 – vaporized hydrogen peroxide is carried via any suitable conduit to the inlet 22 of the sterilization unit 12; See Specification, col. 9, lines 29 to col. 10, line 2 – following the vacuum draw to a first subatmospheric pressure level, injection phases occur a number of times (n). The vaporized hydrogen peroxide is pulsed into the sterilization chamber 12; See Specification, col. 10, lines 3-8 – injection pulses continue, for about ten seconds, until the sterilant vapor concentration is raised to the desired subatmospheric pressure level. The addition of sterilant pulses has been found to enhance sterilant penetration);

holding the hydrogen peroxide in the sterilization unit for a predetermined amount of time (See Specification, col. 9, lines 54-55 – there is a brief hold period, lasting about 15-20 seconds; See Specification, col. 10, lines 17-20 – successive alternating sterilant injection periods and holding periods; See Specification, col. 11, lines), allowing the sterilizing substance to penetrate into the inner sides of the article to be sterilized (See Specification, col. 3, lines 5-7 –

the chamber and devices are in a vacuum when the sterilant is present, penetration into crevices and dead end lumens is enhanced);

introducing a clean gas into the sterilization unit; and holding the clean gas in the sterilization unit for a predetermined amount of time (See Specification, col. 12, lines 25-34 – aeration phase begins with any suitable aeration cycle to be employed, i.e. two to three aeration pulses follow wherein air break valve 48 and exhaust valve 34 are opened for about four seconds, e.g. the predetermined time; See claim 11 – the method further comprising aerating the chamber, following the successive repeating in an alternating fashion the flowing and stopping of the flow of sterilant vapor and air into the chamber a plurality of times, to remove the vapor sterilant from the chamber).

Childers fails to teach (1) that the sterilization unit is a sterilization bag, as claimed in claim 1; (2) the item being sterilized is a rubber gasket for a syringe, as claimed in claims 1 and 8; (3) specific filling rates for the sterilization unit for sterilizing gaskets corresponding to various syringes sizes, as claimed in claims 1-3; (4) that the gasket is sterilized by at least one member selected from the group consisting of active oxygen and radical hydroxide, as claimed in claim 1; (5) that the sterilization treatment comprises a specific number of pulses of aqueous hydrogen peroxide in combination with a specific number of pulses of aeration, as claimed in claims 1-5, in relation to specific filling rates; and (6) setting an outer bag further accommodating the sterilization bag having the article to be processed mounted in a porous container for mounting with a volume rate of 12 to 55%, as claimed in claim 7.

Anderson teaches a sterilization method, comprising filling a sterilization bag (liner bag 16), which holds instruments to be sterilized, at a predetermined rate with a gaseous sterilant (See Specification, col. 2, lines 35-68).

With regard to claim 7, Anderson further teaches a method comprising an outer bag (liner bag 16) accommodating the sterilization bag (gas release bag 14) to be mounted in a porous container (housing 18 with loose fit between the door and the walls of the chamber permitting air to leak into and out of chamber).

The non-patent literature by Stanley Gomez Sdn. Bhd. teaches that syringes consist of three main sections, i.e. the barrel [the lumen], the plunger, and the rubber gasket.

Jacobs teaches a hydrogen peroxide sterilization system, which employs hydrogen peroxide vapor as the precursor for the active species generated during a plasma generation cycle. Jacobs teaches that the term, "plasma" includes any portion of the gas or vapor, e.g. hydrogen peroxide, which contains electrons, ions, free radicals, dissociated and/or excited atoms or molecules produced as a result of the applied electrical field (See Specification, col. 4, lines 8-13). The electrical discharge of hydrogen peroxide generates the dissociated free radical hydroxide. These free radicals, either alone or in combination with hydrogen peroxide, are probably the primary source of sporicidal activity (See Specification, col. 5, lines 34-41).

Regarding missing element (1), it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the sterilization bag of Anderson into the system of Childers as the sterilization unit for holding the instruments to be sterilized because the sterilization bag would have sufficiently served as a compartment for holding the instruments during the sterilization procedure.

Regarding missing element (3), it would have been obvious to one of ordinary skill in the art at the time the invention was made, without undue experimentation, to determine the optimal filling rate in the sterilization bag for a specific item, such as a gasket of a particular size and shape, to be sterilized with the gaseous hydrogen peroxide. Anderson teaches that the gaseous sterilant is released, e.g. the filling rate of the sterilization bag, into the sterilization bag

at a predetermined rate in order to sterilize the instrumentation (See Specification, col. 2, lines 64-68).

Regarding missing element (4), Jacobs provides the motivation and teaching that it is the free radical, either alone or in combination with hydrogen peroxide that probably is the primary source of sporidical activity. Accordingly, it would have been obvious to one of ordinary skill in the art with the teachings of Jacobs to provide for the generation of an anion, such as active oxygen or a hydroxide radical, from the decomposition of gaseous hydrogen peroxide for sterilizing an instrument, such as a gasket, in the sterilizing unit.

Regarding missing element (5), it would have been obvious to one of ordinary skill in the art at the time the invention was made, without undue experimentation, to determine the optimal number of sterilization pulses in combination with the optimal number of aeration pulses in relation to the filling rate of the sterilization unit, as identified in claims 1-5. Childers provides that the precise number of sterilant and aeration injections and the amount of holding time varies depending on the sterilization chamber size, vapor concentration, air flow rate, load size – the gasket size – and sterilization chamber pressure (See Specification, col. 10, lines 34-39).

Regarding missing element (2), it would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt Childers' system for sterilizing various size gaskets for normal and large sized syringes because as Stanley Gomez teaches and as known in the industry of syringes, syringes inherently comprise rubber gaskets. Accordingly, because Childers provides the motivation for sterilizing instruments and other devices having long narrow lumens, e.g. a syringe, it would have been obvious to adapt the filling rate of the sterilization bag and the combination of and number of sterilant and aeration pulses in determining the optimal settings for various size rubber gaskets for normal and large sized syringes to be sterilized.

Regarding claim 8 and missing element (6), it would have been obvious to one of ordinary skill in the art to combine the teachings of Anderson for a sterilization bag, an outer bag, and a container as the sterilization unit into Childers because Childers provides the motivation for a sterilization unit that provides a compartment to hold the sterilized item. Accordingly, one would be able to place the gasket, a relatively small article, into the empty space in the gas release bag 14, which is accommodated within the liner bag 16. It is probable that the liner bag 16 would comprise some articles to be sterilized, too.

5. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Childers, Anderson, non-patent literature by Stanley Gomez Sdn. Bhd., and Jacobs, as applied to claim 1 above, and further in view of Tanaka et. al. [U.S. Patent No. 5,586,975].

Childers, Anderson, the non-patent literature of Stanley Gomez, and Jacobs, teach the subject matter as defined in claim 1 above. They fail to specifically teach the composition of the rubber being at least one of a conjugated or non-conjugated rubber; or a thermoplastic elastomer.

Regarding claim 9, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a suitable material – natural, synthetic, or a blend of rubber, as is common in the construction of syringes – for a syringe that allows the plunger to slide and provides an air and liquid-tight seal, since it has been held within the skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin*, 125 USPQ 416.

Regarding claims 10 and 11, Tanaka teaches a syringe with a slidable gasket, where the gasket is made of thermoplastic elastomer (See Specification, col. 2, lines 20-27). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a

suitable material for a syringe that allows the plunger to slide and provides an air and liquid-tight seal, since it has been held within the skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice. *In re Leshin*, 125 USPQ 416. Accordingly, Childers in view of the other previously mentioned references, provides the motivation for sterilizing the rubber gasket of a syringe, e.g. the gasket made of thermoplastic elastomer taught in Tanaka.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Y. Chin whose telephone number is 571-272-2071. The examiner can normally be reached on Monday – Friday, 8:00 A.M. – 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden, can be reached at 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

byc
February 4, 2005

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